REMARKS

I. Status of the Claims

Claims 39-58 are pending. No claims have been amended by this response.

Applicant acknowledges, with appreciation, the withdrawal of the obviousness-type double patenting rejection.

II. Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claims 39-58 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,514,154 to Lau et al. ("Lau") in view of U.S. Patent No. 5,919,126 to Armini ("Armini") for the reasons stated on 2-4 of the Office Action. Applicants respectfully disagree and traverse this rejection for at least the following reasons.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. M.P.E.P. § 2143.01. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, the prior art can be modified or combined to reject claims as *prima facie* obvious only as long as there is a reasonable expectation of success. M.P.E.P. § 2143.02; *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986).

A. All Limitations Must Be Taught or Suggested

The Examiner alleges that "the product of the Lau et al. in view of Armini is a stent having three layers, a superelastic alloy substrate tube, a first metallic layer and a second metallic radiopaque layer and the stent pattern including a plurality of cylindrical elements and interconnecting elements." Office Action at 3. Applicant disagrees.

Independent claim 39 recites, in relevant part, a laminate stent comprising:

a substrate tube formed from a superelastic alloy and having an exterior surface;

a first cladding layer formed from a metallic material and bonded to the exterior surface of the substrate tube;

a second metallic radiopaque cladding layer bonded to the first layer thereby forming a laminate tube; and

a stent pattern formed in the laminate tube such that the resultant laminate stent includes a plurality of radially expandable cylindrical elements disposed generally coaxially and interconnected by elements disposed between adjacent cylindrical elements. This claim further makes clear that the cylindrical elements and the interconnecting elements being entirely formed of the substrate tube, the first cladding layer, and the second metallic radiopaque cladding layer.

The references of record, alone or in combination, fail to teach each and every element of this claim. For example, Lau discloses an expandable stent made from a tube comprising a pattern of cylindrical structures which plastically deform when expanded. Lau at col. 2, lines 25-52; col. 6, lines 35-50. Lau is silent with respect to cladding layers.

Armini discloses a fundamentally different type of stent from Lau, as well as from what is claimed, having a different structure and made from different materials. The stent of Armini is made of a coated wire that is twisted into a mesh pattern. *See* Armini, Figures 1 and 2. The coating completely surrounds the wire. *Id.*

Neither Lau nor Armini teach or suggest a laminate stent comprising a first cladding layer bonded to the exterior surface of a substrate tube, a second metallic radiopaque cladding layer bonded to the first layer, and a stent pattern comprising radially expandable cylindrical elements and interconnecting elements entirely formed of the substrate tube, the first cladding layer, and the second cladding layer. Thus, the references fail to teach all of the structural limitations recited in the present claims because Lau and Armini do not teach or suggest the use of cladding layers on a substrate tube to form a laminate stent. For this reason alone, the Examiner's rejection is improper and should be withdrawn.

B. Motivation to Combine

The Examiner asserts that it would have been obvious to one skilled in the art to "employ the layers as claimed into Lau et al.'s stent tube in order to provide a stent with improved X-ray visibility." *See* Office Action at 2. Applicant disagrees.

One of ordinary skill in the art would not have been motivated to employ the layers taught by Armini on the stent of Lau because the dissimilarities of the stents lead one to objectively conclude that there is no reasonable expectation of success in the Examiner's combination. As explained above, Lau teaches a stent that does not

comprise any cladding layers. Armini, while teaching additional layers, discloses the use of coated wires, which are twisted to form a mesh pattern.

The different structures of the Lau and Armini stents are subjected to different forces when deployed. For example, Lau discloses that upon expansion, "portions of the undulating pattern will tip outwardly resulting in projecting members of the outer surface of the expanded stent." Lau at col. 2, lines 35-52. The degree of expansion disclosed by Lau ranges from an unexpanded diameter of 0.06 inch to an expanded diameter of 0.1 inch or more. *Id.* at col. 6, line 61 to col. 7, line 3.

In contrast, the stent of Armini is formed of twisted wires, inevitably leading to different forces along the length of the individual wires of the stent. Thus, one skilled in the art would recognize that while the stent of Armini is exposed to simple bending forces, the cylindrical elements of the Lau stent are exposed to rotational and torsional forces upon expansion. Such forces greatly increase the chance of delamination of laminated layers, such as laminated layers recited in the present claims.

Based on the teachings and knowledge available at the time of invention to one of ordinary skill in the art, the skilled artisan would not have been motivated to modify the uncoated tube-based stent of Lau by bonding first and second cladding layers to a substrate tube and forming a stent pattern in the laminate tube formed thereby. One skilled in the art would not have had a reasonable expectation of success in modifying the uncoated stent of Lau to have cladding layers formed on the exterior of the substrate tube because Armini teaches a structurally distinct form of stent that uses coated wires having coatings that are formed by sputtering to completely surround the

wires. Because of the distinct forms of stents taught by Lau and Armini, one skilled in the art would not have reasonably expect cladding layers bonded to the exterior of a substrate tube to perform adequately in light of the risk of delamination.

C. Equivalence

With respect to claims 45-57, the Examiner acknowledges that Lau and Armini do not teach the claimed materials. The Examiner nevertheless asserts that the claimed materials would have been an obvious matter of design choice because "applicants has not disclose [sic] that having such specific materials as claimed solve any stated problem or for any particular purpose and it appears that the stent would perform equally well with material as disclosed by Lau et al. in view of Armini or materials as claimed or other materials known in the art." Office Action at 2-3. Applicant disagrees.

The Examiner has failed to establish a *prima facie* case of obviousness because the references admittedly neither teach nor suggest the materials claimed. In addition, the references fail to establish the equivalence of the claimed materials and the materials disclosed by Lau and Armini. *See* M.P.E.P. § 2144.06. Moreover, Applicant clearly discloses that materials "facilitate consistent tube diameter and wall thickness reduction while minimizing the chance of delamination of the concentric tubes." *See* Specification at page 10, lines 3-16. For at least these reasons, Applicant respectfully submits that the rejection is improper and requests the withdrawal of the rejection.

D. Product-By-Process Claims

The Examiner asserts that claims 56-58 are product-by-process claims and that the combination of Lau and Armini teach the product recited in the present claims. Applicant disagrees.

As previously shown, the combination of Lau and Armini does not have the same structure as the claimed laminate stent. Armini discloses a wire stent that is coated by sputtering, which produces wires completely surrounded by the coating. Armini at col. 5, lines 16-24; Figure 2. In contrast, the present claims recite a laminate stent comprising, *inter alia*, a substrate tube and a first cladding layer bonded to the exterior surface of the substrate tube. Therefore, the combination of Lau and Armini differs structurally from the present invention because the combination of Lau and Armini does not result in a laminate stent as claimed.

Furthermore, not only do the process steps recited in the present claims clearly distinguish over the prior art, but they lead to a product that distinguishes the claimed invention over the combination of Lau and Armini. The step of bonding and cold drawing facilitates a mechanical bond and minimizes delamination of the materials. *See* Specification at page 11, line 19 to page 12, line 9. Heat treating the layers releases stress and eliminates restrained dislocations. *Id.* at page 12, lines 16-17. Forming the pattern by chemical etching and laser cutting also distinguishes the claimed invention from the combination of Lau and Armini. As explained above, Lau does not disclose any cladding layers, and Armini discloses sputtering the wire to form a coating that completely surrounds the core of the wire. Armini, Figure 2. In contrast, the process of

chemical etching and laser cutting results in the claimed laminate structure, which comprises the substrate tube, the first cladding layer, and the second cladding layer.

For at least the following reasons, Applicant submits that the combination of Lau and Armini fails to meet any of the three requirements of obviousness, including teaching all of the structural features presently claimed, providing a proper motivation for combining the disparate reference teachings, or showing a likelihood of success if such teachings were combined. For these reasons, Applicant respectfully requests the reconsideration and withdrawal of the rejection.

III. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims 39-58.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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/Louis Troilo/

Dated: May 12, 2006 By:_____

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